K042099

DEC 1 0 2004

510(k) SUMMARY

1 Submitter (Contact) Information

A Company Name/Address: RetinaPharma Technologies, Inc.
944 Morgan Road
Jenkintown, PA 19046

B Company Phone: (215) 885-4558

C Company Fax: (215) 885-2788

D Contact Person: Terry A. Fuller, Ph.D.
President

E Manufacturing Location: The Company has not established a manufacturing facility. It will notify the Agency upon its establishment.

2 Device Information

A Device Trade Name: TonoPach™ Ultrasonic Tonometer/Pachymeter
Model P-201 (the "TonoPach™")

B Device Classification:
The TonoPach is a combination of two devices, a pneumatometer and a pachymeter, which have already been determined to be substantially equivalent to legally marketed predicate devices with regard to safety, effectiveness and intended use. The device classifications are presented in the following table.

	Pneumatometer	**Pachymeter**
Common Name:	Tonometer for Measuring Intraocular Pressure	Ultrasonic Pachymeter for Measurement of Corneal Thickness
Classification Name:	Tonometer, AC Powered	Ultrasonic Pulsed Echo Imaging System
Product Code:	HKX	90-IYO
Regulatory Class & Tier:	II	II
Regulatory Number:	21 CFR 866.1930	21 CFR 892.1560
Classification & Review Advisory Committees	Ophthalmic	Radiology

3 Substantial Equivalence

The RetinaPharma TonoPach Ultrasonic Tonometer/Pachymeter is judged to be substantially equivalent in safety, effectiveness and intended use to the following legally marketed devices:

List of predicate devices

Predicate Device	Manufacturer	510(k)	Date Cleared
Tonometer			
TonoPen ophthalmic tonometer	Oculab, Inc.	K 852774	August 20, 1985
Pachymeter			
Pocket Ultrasonic Pachymeter	Quantel Medical, Inc.	K993674	July 13, 2000
Echoscan Model US-1800	Nidek, Inc.	K020876	May 3, 2002

4 Device Description.

The TonoPach is a portable, battery operated, handheld ophthalmic instrument which measures both intraocular pressure (IOP) and corneal thickness (CT) simultaneously and at the same locus on the cornea. The device uses the principles of applanation pneumatometery to measure IOP and the principles of reflection pulsed ultrasound pachymetry to measure CT. The system is comprised of the TonoPach electronics, transducer handpiece, protective membranes and optionally, a foot pedal.

5 Intended Use

The TonoPach Ultrasonic Tonometer/Pachymeter Model P-201 is a diagnostic instrument that is intended for use in the measurement of both intraocular pressure and corneal thickness. It is intended for use during or following surgery and as a screening, monitoring or diagnostic aid in patients with normal, disease-induced or surgically altered anatomy, or in glaucoma suspects under current therapeutic guidelines.

6 Technological Equivalence

Table 6.1 provides a list of predicate devices and the "k" number. In Tables 6.2, 6.3 and 6.4 the TonoPach Pachymeter portion and the Ultrasonic Tonometer are compared, respectively, to predicate devices to show the equivalence. Description statements were relied on to ascertain the intended use and technological features of legally marketed devices, and the substantial equivalence to the TonoPach to such legally marketed devices. The comparison of the intended use and technological features of this device to other legally marketed devices indicates that this device is substantially equivalent to legally marketed predicate devices with regard to safety, effectiveness and intended use. Note: areas of difference between the two devices are indicated in the tables. RetinaPharma believes that these differences are minor and should not raise any concerns regarding the overall safety and efficacy of the TonoPach.

Table 6.1: List of predicate devices

Predicate Device	Manufacturer	510(k)	Date Cleared
Tonometer			
TonoPen ophthalmic tonometer	Oculab, Inc.	K 852774	August 20, 1985
Pachymeter			
Pocket Ultrasonic Pachymeter	Quantel Medical, Inc.	K993674	July 13, 2000
Echoscan Model US-1800	Nidek, Inc.	K020876	May 3, 2002

Table 6.2: Comparison of Tonometer Characteristics TonoPen vs. TonoPach P 201		
	Predicate Device Mentor TonoPen 3	RetinaPharma TonoPach P 201
Measurement	IOP	IOP
Pressure measurement device	Micro strain gauge	Micro strain gauge
Measurement technique	Applanation	Applanation
Pressure range	5-80 mm Hg	5-80 mm Hg
Pressure contact area*	1.5 mm	1.8 mm
Measurement frequency	500 reading per second	500 readings per second
Display/measure	LCD / 2 digit reading	LCD / 2 digit reading
Statistical storage	Yes	Yes
Pressure traceability	Manometer & Goldmann	Manometer & Goldmann
Usage	Handheld	Handheld or Slitlamp mounted
Power supply	Battery	Battery
System configuration*	Single unit; transducer and system electronics combined	Tethered unit; transducer is tethered from the system electronics
Versatility	Can be used with the patient in any position, making it suitable for use in the office, bedside or in remote locations. Suitable for use in cases of their regular or Hg corneal astigmatism.	Can be used with the patient in any position, making it suitable for use in the office, bedside or in remote locations. Suitable for use in cases of their regular or Hg corneal astigmatism.
*Indicates differences between the predicate device and TonoPach		

Table 6.3: Comparison of Pachymeter Characteristics "Pocket" Ultrasonic Pachymeter and Echoscan US-1800 vs. TonoPach P 201			
	Predicate Device "Pocket"	Predicate Device Echoscan US-1800	RetinaPharma TonoPach P 201
Measurement	Corneal thickness	Corneal thickness	Corneal thickness
Measurement system	Ultrasonic pulse reflection	Ultrasonic pulse reflection	Ultrasonic pulse reflection
Probe type	Solid, Angled	Solid, Straight, Angled	Solid Straight, Angled
Measurement range*	100 to 1300 um	200 to 1300 um	125 to 1300 um
Clinical accuracy	+/- 5 um	+/- 5 um	+/- 5 um
Least significant display digit	1 um	1 um	1 um
Default velocity*	1620 m/sec	1640 m/sec, changeable	1640 m/sec
Exam Mode(s)	Single point, 1 map	Single point, 3 maps	Single point, 1 map
Data Output	LCD, Print	LCD, Print	LCD, Print
Power requirements	Battery	120 VAC, 60 Hz	Battery
Weight	0.46 kg	6 kg	0.75 kg
*Pachymeter mode. Indicates difference between the predicate device and the TonoPach.			

7 TonoPach Testing

Substantial testing has been performed using the TonoPach. It includes inanimate, animal and human evaluation.

A Inanimate: Models for both tonometry and pachymetry have been used.
   1) The tonometry model consists of a water-filled spherical membrane attached to a manometer. When the TonoPach handpiece tip touches the sphere, it mimics intraocular pressure.
   2) The pachymetry model consists of polycarbonate wafers of varying thicknesses. When the TonoPach handpiece tip touches a wet wafer, it is suitable to mimic the cornea for thickness measurement purposes.

B Animal: Live rabbit eyes and freshly enucleated porcine eyes were used for several studies.
   1) Rabbit eyes were used to test the tonometer and pachymeter portions of the TonoPach. They were used to evaluate the TonoPach's performance on a live eye. Also, they were used to assist in evaluation of the System's numerical accuracy and reproducibility.
   2) Pig eyes were used predominately to verify and validate tonometer accuracy and reproducibility. One study was used to demonstrate repeatability. Three porcine eyes were studied at each 10 mmHg pressure over a pressure range of 5 to 80 mmHg with 10 independent measurements per pressure. The data exceeds product specifications.

C Clinical Crial: The TonoPach was evaluated on eye clinic volunteers who required tonometery. All patients who agreed to volunteer were admitted to the study.
   1) Tonometry testing was the predominated the data collected. 347 eyes were tested for comparison to Goldmann tonometery. Scatter and Bland & Altman plots as well as mean, standard deviation and variance around the mean reveal that the TonoPach meets or exceeds specifications.

8 Statement of Confidentiality

Information contained in this letter and its attachments is considered confidential, proprietary information and a trade secret until RetinaPharma Technologies, Inc. distributes such information publicly. The release of information contained herein is to be governed by applicable provisions of the Food, Drug and Cosmetic Act, the Freedom of Information Act and pertinent FDA regulations in 21 CFR Part 20.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 0 2004

RetinaPharma Technologies, Inc.
% Terry Fuller, Ph.D.
944 Morgan Road
Jenkintown, PA 19046

Re: K042099
Trade/Device Name: TonoPach Ultrasonic Tonometer/Pachymeter Model P-201
Regulation Number: 21 CFR 886.1930
Regulation Name: Tonometer and accessories
Regulatory Class: Class II
Product Code: HKX
Dated: July 30, 2004
Received: August 4, 2004

Dear Dr. Fuller:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

3) Diagnostic Ultrasound Indications for Use Form

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510(k) Number (if known):

Device name: RetinaPharma Model P 201, TonoPach™ System

Intended Use: The TonoPach Ultrasonic Tonometer/Pachymeter Model P-201 is a diagnostic instrument that is intended for use in the measurement of both intraocular pressure and corneal thickness. It is intended for use during or following surgery and as a screening, monitoring or diagnostic aid in patients with normal, disease-induced or surgically altered anatomy, or in glaucoma suspects under current therapeutic guidelines.

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic	N									
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)*										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ (Per 21 CFR 801.109)

Clay R. Butterworth

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K042099